

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/698,076	
			Filing Date	October 29, 2003	
			First Named Inventor	Cynthia B. Robinson	
			Art Unit	1617	
			Examiner Name	Umamaheswari Ramachandran	
Sheet	1	Of	4	Attorney Docket Number	30775-714.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US 2003/0216329	11/20/2003	Robinson et al.	
	2.	US 2004/0067920	04/08/2004	Leonard et al.	
	3.	US 2004/0082522	04/29/2004	Hui	
	4.	US 2005/0101544	05/12/2005	Robinson, et al.	
	5.	US 3,536,809	10/27/1970	Applezweig	
	6.	US 3,598,123	08/10/1971	Zaffaroni	
	7.	US 3,630,200	12/28/1971	Higuchi, et al.	
	8.	US 3,845,770	11/05/1974	Theeuwes, et al.	
	9.	US 3,916,899	11/04/1975	Theeuwes, et al.	
	10.	US 4,008,719	02/22/1977	Theeuwes, et al.	
	11.	US 4,208,423	06/17/1980	Pfister	
	12.	US 4,501,729	02/26/1985	Boucher et al.	
	13.	US 4,859,692	08/22/1989	Bernstein, et al	
	14.	US 4,956,355	09/11/1990	Prendergast	
	15.	US 5,294,636	03/15/1994	Edwards, et al.	
	16.	US 5,319,097	06/07/1994	Holohan, et al.	
	17.	US 5,482,963	01/09/1996	Holohan, et al.	
	18.	US 5,527,789	06/18/1996	Nyce	
	19.	US 5,565,473	02/23/1995	Belley, et al.	
	20.	US 5,583,152	12/10/1996	Bernstein, et al	
	21.	US 5,603,918	02/18/1997	McNamara	
	22.	US 5,612,367	03/18/1997	Timko, et al.	
	23.	US 5,660,835	08/26/1997	Nyce	
	24.	US 5,859,000	01/12/1999	Dowell et al.	
	25.	US 5,955,058	09/21/1999	Jager et al.	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/698,076	
			Filing Date	October 29, 2003	
			First Named Inventor	Cynthia B. Robinson	
			Art Unit	1617	
			Examiner Name	Umamaheswari Ramachandran	
Sheet	2	Of	4	Attorney Docket Number	30775-714.201

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	26.	US 6,087,351	07/11/2000	Nyce	
	27.	US 6,143,775	11/07/2000	Holohan, et al.	
	28.	US 6,299,861	10/09/2001	Banholzer et al.	
	29.	US 6,455,524	09/24/2002	Bozung et al.	
	30.	US 6,635,629	10/21/2003	Raymond et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ² - Number ³ - Kind Code ⁴ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁵
	31.	EP 115394 B1	06/28/1989	Guindon, et al		
	32.	EP 136893 B1	08/16/1998	Fortin, et al		
	33.	EP 138481 B1	06/26/1991	Fortin, et al		
	34.	EP 140709 B1	04/03/1991	Atkinson, et al.		
	35.	EP 429187 B1	01/05/1994	Bourke et al.		
	36.	EP 934745 B1	04/28/2004	Kennedy		
	37.	GB 2,240,472 A	08/07/1991	Masterson		
	38.	WO 91/04030 A1	04/04/1991	Daynes et al.		
	39.	WO 96/25935 A1	08/29/1996	Nyce		

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/698,076
				Filing Date	October 29, 2003
				First Named Inventor	Cynthia B. Robinson
				Art Unit	1617
Examiner Name	Umamaheswari Ramachandran				
Sheet	3	Of	4	Attorney Docket Number	30775-714.201

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶		
	40.	ABOU-GHARBA, et al. Synthesis of dehydroepiandrosterone sulfate and 16 alpha-halogenated steroids. J Pharm Sci. 1981; 70(10):1154-7.			
	41.	BUNDGAARD et al. Esters of N,N-disubstituted 2-hydroxyacetamides as a novel highly biolabile prodrug type for carboxylic acid agents. J. Med Chem. 1987; 30(3):451-454.			
	42.	DASHTAKI et al. Dehydroepiandrosterone and Analogs Inhibit DNA Binding of AP-1 and Airway Smooth Muscle Proliferation. J. Pharmacol. EXD. Thera. 285(2):876-83 (1998).			
	43.	FOLKERS, et al. Lovastatin decreases coenzyme Q levels in humans. Proc Natl Acad Sci U S A. 1990;87(22):8931-4.			
	44.	GREENBERG, et al. Co-enzyme Q10: a new drug for cardiovascular disease. J Clin Pharmacol. 1990; 30(7):596-608.			
	45.	ISHIHARA, et al. Gas chromatographic determination of degradation products and stability of dehydroepiandrosterone. Drug Develop. Ind. Pharm. 1979; 5(3):263-275.			
	46.	MERCK Index Monograph No. 7710. 11th Ed. 1989.			
	47.	MOHAN, et al. Dehydroepiandrosterone and related steroids inhibit mitochondrial respiration in vitro. Int J Biochem. 1989; 21(10): 1103-7.			
	48.	MORTENSEN, et al. Coenzyme Q10: clinical benefits with biochemical correlates suggesting a scientific breakthrough in the management of chronic heart failure. Int J Tissue React. 1990;12(3):155-62.			
	49.	NAKAGAWA, et al. The effect of grinding and drying on the solid state stability of sodium prasterone sulfate. Chem. Pharm. Bull. 1982; 30(1):242-8.			

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. ¹Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ²Applicant's unique citation designation number (optional). ³See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ⁴Enter office that issued the document, by the two-letter code (WIPO Standard ST 3). ⁵For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁶Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST 16 if possible. ⁷Applicant is to place a check mark here if English language translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 USC 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Under the paperwork Reduction Act of 1995, no persons required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known		
				Application Number	10/698,076	
				Filing Date	October 29, 2003	
				First Named Inventor	Cynthia B. Robinson	
				Art Unit	1617	
Examiner Name	Umamaheswari Ramachandran					
Sheet	4	Of	4	Attorney Docket Number	30775-714.201	

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	50.	NAKAGAWA, et al. the properties of water of crystalization of sodium prasterone sulfate. Chem. Pharm. Bull. 1981; 29(5):1466-9.	
	51.	SAARI, et al. Synthesis and antihypertensive activity of some ester progenitors of methylodpa. J. Med. Chem. 1978; 21(8):746-753.	
	52.	SAKAMOTO, et al. Studies on prodrugs. II. Preparation and characterization of (5-substituted 2-oxo-1,3-dioxolen-4-yl)methyl esters of ampicillin. Chem. Pharm. Bull. 1984; 32(6):2241-2248.	

UNPUBLISHED PATENT APPLICATIONS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	53.	LEONARD, et al. US Patent Application No. 10/462,927, entitled "Dihydrate dehydroepiandrosterone and methods of treating asthma or chronic obstructive pulmonary disease using compositions thereof," filed June 17, 2003. (WSGR Reference No. 30775-722.201)	

Examiner Signature	Date Considered
--------------------	-----------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.15 if possible. ⁶Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.